MARKOS KYPRIANOU
MEMBER OF THE EUROPEAN COMMISSION

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MEMBER OF THE EUROPEAN COMMISSION

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Mrs Michelle Childs
Consumer Project on Technology
24 Highbury Crescent
London N5 1RX
United Kingdom

Dear Mrs Childs,

Thank you for your letter of 19 October 2005 in which you raise concerns regarding the announcement of the EU Member States not to use the compulsory licensing mechanism based on the WTO General Council Decision of 30 August 2003 in the context of availability of antiviral drugs and vaccines.

The compulsory licensing mechanism foreseen in the WTO Decision was adopted in the interest of countries not having their own pharmaceutical production facilities. Without the decision, these countries would have been prevented from using compulsory licensing as a means to get access to generic medicines, given that the TRIPs Agreement allows the grant of compulsory licenses only *"predominantly for the supply of the domestic market"*.

The EU and its Member States have production facilities for pharmaceutical products. Indeed, Europe has a very competitive pharmaceutical industry (both innovative and generic), which successfully exports its products to all other regions of the world. The EU Member States can therefore use the compulsory licensing mechanism foreseen under Article 31 of the TRIPs Agreement without needing to rely on the Decision of 30 August 2003.

Given that the EU is a single market, pharmaceutical products can circulate freely even if originally brought on the market in only one Member State. Against this background, a patent cannot normally be used to prevent a Member State from purchasing drugs produced and marketed in other Member States.

For these reasons, the European Commission does not consider that the declarations made by EU Member States in the context of the adoption of the WTO General Council Decision of 30 August 2003 will create an obstacle for supplying the domestic market with the required drugs and vaccines.

By contrast, withdrawing these declarations, which constitute an important element in the decision of Contracting Parties to agree to the waiver, could undermine the basis on which the Decision was adopted. This would certainly not be in the interest of countries without production facilities for which the Decision was made. In that context it should be emphasized that pandemic flu is a global health risk, and it is in the European Union's own interest that the Decision remains in place so that all countries can have access to the drugs and vaccines in question.

The European Commission recognises the importance of preparing for a potential influenza pandemic by ensuring the supply of vaccines and antivirals. As we do not know the specific virus strain that may cause a pandemic, it is not possible to stockpile large amounts of vaccine in advance. Nevertheless, the EU has taken steps, through establishing a Public Private Partnership (PPP) with the pharmaceutical industry, to ensure that once the strain is identified, the production of vaccine can take place without delay. These steps include an agreement with industry to submit dossiers to the European Medicines Agency (EMEA) for a 'mock-up' or template vaccine as soon as possible. This process will reduce work needed to license the vaccine for the pandemic strain at the time it is needed.

It is, however, possible to stockpile antiviral drugs. The Commission is encouraging EU Member States to place orders with the leading European producers of antivirals for stockpiling. Commissioner Kyprianou has met with the major producer, Roche, to share views and to ensure an ongoing dialogue on this important public health issue. Roche is working to increase their its production capacities and has made a commitment that patents will not stand in the way of increasing its product, and is actively working with third parties who have expressed interest in manufacturing the drug.

We hope you find this information helpful.

Yours sincerely,

Markos KYPRIANOU

Peter MANDELSON